

Imaging as a Biomarker: Standards for Change Measurements in Therapy

Breakout Area 4: Open Architecture & Software Tools:
Image and Meta-data Collection and Analysis,
Data Integration and Display

Day 2: Summary

“The Detailed Measurement Science & Standards Needs –
The What by When and by Whom”
Near, Mid-Term Issues Only

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Measurement Needs

(From Yesterday)

Near Term

1. Management of Metadata and Ontologies
2. “Plug-in” or Service Oriented Architectures
3. Reference Implementations

Mid Term

1. Management of Metadata and Ontologies
2. System Quality Management
3. Interacting with Workflow Engines
4. Data Collection Protocol Management

Long Term

1. Automation of Processing

Breakout Area 4: Open Architecture & Software Tools:
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Measurement Need #2 for Mid-Term 3-5 Years

1. *Technology at Issue:* Management of Data Collection Quality Control
 - “Data Collection Quality Control” includes not just the measurement system, but how the measurement system was used.
 - Also may include the analysis of the collected data
2. *Submitter(s):* Participants of Breakout Area 1
3. *Technological Innovation at Stake:*
 - Mechanism to move fundamental quality checks to scan time, giving immediate feedback to technologists and researchers
 - Mechanism for data collection centers to collect the QC measurements along with the measurement data
 - QC data must be in a machine-readable form
 - Analysis must be automated
4. *Economic Significance of Innovation:*
 - Immediate feedback and reduced variability may reduce the number of non-evaluable studies, thus reducing the number of subjects that must be enrolled to get statistically sound data

Breakout Area 4: Open Architecture & Software Tools:
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Measurement Need #2 for Mid-Term 3-5 Years (cont'd)

5. Technical Barrier to the Innovation:

- Resistance of manufacturers to sharing QC data - getting access to the data needed for the QC assessment
- Criteria for QC for a given study generally provided by an off-site entity
- Architecture needs to be open, “plug-inable” QC, deployable to multiple sites with differing equipment
- Getting feedback to the operators, particular when the QC analysis is done off-site
- Must be easy to use, minimally disruptive

6. Stage of Innovation Where Barrier Appears:

- *R&D (During equipment product feature specification & during product release*
- *End Use*

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Measurement Need #2 for Mid-Term 3-5 Years (cont'd)

7. *Measurement-Problem Part of Technical Barrier.*

- Characterizing the instrumentation
- Characterizing the drift
- Characterizing the data collection
- Interoperability of the data

8. *Potential Solutions to Measurement Problem:*

- Common ontological framework
- Method for describing the phantom
- Method for automating the measurement
- Method for automating the analysis of the measurements
- Method for returning measurement results to the site, and incorporate corrections into the measurement process

**Breakout Area 4: Open Architecture & Software Tools:
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Measurement Need #4 for Mid-Term 3-5 Years (cont'd)**

9. Potential Providers of Solutions:

- AAPM (Physicists)
- Phantom Manufacturers (Physicists)
- DICOM
- Equipment and Software Manufacturers
- CROs

10. What is the role for Government, if Any?:

- Create appropriate measurements (phantom specification, acquisition setup, analysis, etc.)
- Characterize and/or mandate particular measures
- Manage ontology, cooperating internationally
- Provide reference implementations of the collection, analysis, and dissemination architecture
- Provide neutral archives (e.g., for tracking, for improving equipment)
- Provide [secure] communications infrastructure

11. If There is a Government Role, Why Industry Says It Can't / Won't Pay for That Part of Solution:

- No economic incentive to equipment manufacturers for providing such tracking

Breakout Area 4: Open Architecture & Software Tools:
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Measurement Need #4 for Mid-Term 3-5 Years

1. *Technology at Issue:* Data collection protocol management, High and Low Level
2. *Submitter(s):* Participants of Breakout Area 1
3. *Technological Innovation at Stake:*
 - Ability to consistently produce measurable images at multiple sites with differing equipment that has similar capabilities
4. *Economic Significance of Innovation:*
 - More consistent data collection, reducing variability, and thus reducing the number of participants needed to obtain statistically significant data

Breakout Area 4: Open Architecture & Software Tools:
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Measurement Need #4 for Mid-Term 3-5 Years (cont'd)

5. Technical Barrier to the Innovation:

- Proprietary nature of how manufacturers control their measurement instruments
- Variability in the capabilities of equipment
- Variability in how different equipment accomplishes similar tasks

6. Stage of Innovation Where Barrier Appears:

- R&D

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Measurement Need #4 for Mid-Term 3-5 Years (cont'd)

7. *Measurement-Problem Part of Technical Barrier:*

- How to represent the low level settings in a vendor-neutral method?
- Consistent ontologies for describing acquisition and other data collection parameters
- Describing patient-prep, monitoring, etc.
- Automating measurements that require a feedback loop (i.e., data collection contingent on events during data collection)

8. *Potential Solutions to Measurement Problem:*

- Document distribution for the high level portion
- Sample scanner settings (one for each scanner type in the trial) for the low level settings for acquisition (scanner translates into the internal representation)
- “Plug-in” distribution for analysis methods needed by the protocol

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Measurement Need #4 for Mid-Term 3-5 Years (cont'd)

9. Potential Providers of Solutions:

- UPICT
- NEMA/DICOM (for the standard mechanism for describing scanner settings)

10. What is the role for Government, if Any?:

- Archive for data collection protocols (e.g. NCI/NLM)
- Ontology management, coordinated internationally (e.g. NLM)
- Gap analysis – are there units of measure that would be needed to characterize a data collection protocol, including acquisition parameters? (e.g. NIST)

11. If There is a Government Role, Why Industry Says It Can't / Won't Pay for That Part of Solution:

- Need a neutral third party
- Getting around the barrier of manufacturer proprietary information